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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,745	12/21/2001	James A. Brady	9386.17711-C	4890

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EXAMINER
BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	10/036,745	BRADY ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *15-25 and 50-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 26-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-14 and 26-49, in Paper No. 6 is acknowledged.

Please note that the election requirement was incomplete for the claim grouping of the elected invention, Group I. Claims 11-14 and 26 were inadvertently left out of the grouping. However, they have been included in the election and have been acted upon in this office action.

2. Claims 15-25 and 50-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirai et al. (5,902,877). Hirai et al. (hereafter Hirai) discloses an adsorbant system having an inlet and outlet for fluid (1/2), and an adsorbant means (3) within a column 6 and a vessel 7 or housing. The adsorbant means is a styrene-divinylbenzene copolymer. The system is used for removing interleukins (i.e. cytokines) from a body fluid. The body fluid may be ascites, lymph, or synovial fluids. Claim 1 recites a flow path "adapted to draw a physiologic fluid" and it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. With respect to the claimed limitations of claims 2-6, the fluids are not given patentable weight since they were not positively recited in claim 1 and are a product of the intended use of the device. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC § 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller.* With respect to claims11-14, the recitation that the polymeric material is "prepared by" a process has not been given patentable weight since it is a product-by-process limitation. "Even though product-by-process claims are limited by

and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai ('362). Hirai discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the adsorption medium is characterized by a Biocompatibility Index of not greater than 14, or not greater than 7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric material of the adsorbant to be characterized by a Biocompatibility Index of not greater than 14, or not greater than 7, since it has been held in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

6. Claims 26-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai et al. ('362) in view of Okarma et al. (5,437,861). Hirai et al. (hereafter Hirai) discloses an adsorbant system having an inlet and outlet for fluid (1/2), and an adsorbant means (3) within a column 6 and a vessel 7 or housing. The adsorbant means is a styrene-divinylbenzene copolymer. The system is used for removing interleukins (i.e. cytokines) from a body fluid. The body fluid may be ascites, lymph, or synovial fluids. With respect to the claimed limitations of claims 27-31, the fluids are not given patentable weight since they were not positively recited in claim 26 and are a product of the intended use of the device. With respect to claims 34-37 & 46-49, the recitation that the polymeric material is "prepared by" a process has not been given patentable weight since it is a product-by-process limitation. "Even though product-by-process claims are limited by and defined by the process, determination of patentability

is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Hirai discloses the invention substantially as claimed, however, fails to disclose specifically that a means for drawing a physiologic fluid from a body region and a means for circulation of the physiological fluid outside the individual for return to the body are part of the system and a method for using the system wherein the fluids are peritoneal dialysis solution, CSF, or spinal fluid.

Hirai does disclose that the fluid may be ascites, or an accumulation of fluid in the peritoneal cavity, therefore in the broadest interpretation of the claims, this includes peritoneal dialysis solution since it inherently accumulates in the peritoneal cavity to perform its dialyzing function. With respect to the fluid being CSF or spinal fluid, it would have been obvious to choose either, based on the treatment required for a specific patient, since interleukins are widely present in both fluids during infection.

Okarma et al. discloses a device for the removal of selected factors, such as cytokines, from body fluid, namely blood, using tubing for withdrawal and circulation outside of the body through the adsorbant device and then for returning to the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inlet and outlet ports of the system of Hirai to include tubing as taught by Okarma for withdrawing, circulating through the system, and returning to the

individual such that the interleukins would be removed from the fluid and treated fluid is then returned to the patient. Such a modification would have been obvious since it is implied in Hirai that fluid is withdrawn from a patient, enters the column via an inlet, passes through the adsorbant, exits the column via the outlet and is returned.

Conclusion

7. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb
June 29th, 2003